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PATENT

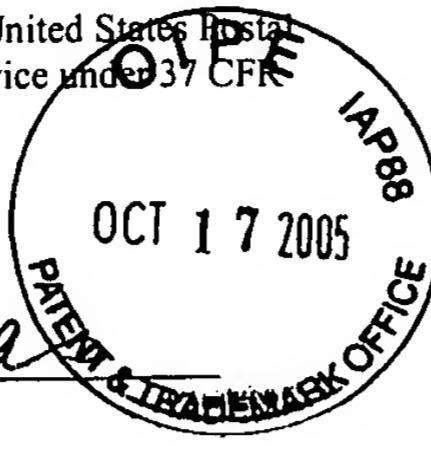
Attorney Docket No.: 010692-004532US

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Commissioner for Patents
P.O. Box 1450

Alexandria, VA 22313-1450

By: Marta Vanega



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gorfine, Stephen R.

Application No.: 10/669,099

Filed: September 22, 2003

For: NITRIC OXIDE DONOR
COMPOSITION AND METHOD FOR
TREATMENT OF ANAL DISORDERS

Examiner: Tate, Christopher Robin

Art Unit: 1654

**INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §1.97 and
§1.98**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the U.S. patent references (Ref. Nos. 1-24) are not submitted [in compliance with the requirements of 1287 OG 163].

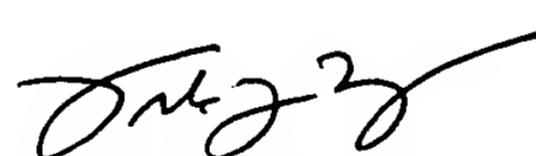
In accordance with 37 CFR 1.95(d), copies of foreign patent Ref. Nos. 25-34 and non-patent Ref. Nos. 38-76 are to be found in U.S. Patent Appln. Nos. 08/250,555 (filed May 27, 1994, Patent No. 5,504,117, Atty. Ref. 010692-004500US); 08/371,088 (filed Jan. 10, 1995, abandoned, Atty. Ref. 010692-004510US); 08/666,264 (filed Jun. 20, 1996, Patent No. 5,693,676, Atty. Ref. 010692-004520US); 08/970,447 (filed Nov. 14, 1997, abandoned, Atty. Ref. 010692-004530US); and 10/021,168 (filed Dec. 11, 2001, abandoned, Atty. Ref. 010692-

004531US). Additional copies of these references may be provided to the Examiner upon request. Copies of the remaining references (Ref. Nos. 33-35 and 77-104) are submitted herewith. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This Statement is submitted concurrently with a Request for Continued Examination. Accordingly, no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Frank J. Mycroft
Reg. No. 46,946

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 925-472-8895
FJM:mrv
60610458 v1



Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	7	Attorney Docket Number	010692-004532US
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Complete if Known

Application Number	10/669,099
Filing Date	September 22, 2003
First Named Inventor	Gorfine, Stephen R.
Art Unit	1654
Examiner Name	Tate, Christopher Robin

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. ¹	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
1	US-814,408	03-06-1906	Steele		
2	US-2,840,080	06-24-1958	Clark		
3	US-3,419,571	12-31-1968	Di Carlo et al.		
4	US-4,118,480	10-03-1978	Williams		
5	US-4,226,849	10-07-1980	Schor		
6	US-4,292,299	09-29-1981	Suzuki et al.		
7	US-4,371,516	02-01-1983	Gregory et al.		
8	US-4,514,384	04-30-1985	Gallina		
9	US-4,608,249	08-26-1986	Otsuka et al.		
10	US-4,654,209	03-31-1987	Leslie et al.		
11	US-4,657,906	04-14-1987	Emmet et al.		
12	US-4,683,242	07-28-1987	Poser		
13	US-4,746,675	05-24-1988	Makino et al.		
14	US-4,842,854	06-27-1989	Babaian et al.		
15	US-5,047,230	09-10-1991	Nagy et al.		
16	US-5,059,603	10-22-1991	Rubin		
17	US-5,085,650	02-04-1992	Giglio		
18	US-5,183,663	02-02-1993	Greiner		
19	US-5,439,938	08-08-1995	Snyder et al.		
20	US-5,504,117	04-02-1996	Gorfine		
21	US-5,508,045	04-16-1996	Harrison et al.		
22	US-5,595,753	01-27-1997	Hechtman		
23	US-5,595,970	01-21-1997	Garfield et al.		
24	US-5,693,676	12-07-1997	Gorfine		

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Number ⁴	Country Code ³ Kind Code ⁵ (if known)				
25	DE	304,730		03-01-1989	Dunzendorfer et al.		<input type="checkbox"/>
26	AU	74545/94		08-19-1994	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
27	AU	PM 0971		03-22-1995	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
28	AU	PM 4247		03-22-1995	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
29	AU	PM 6395		07-14-1994	Koren Laboratories Pty., Ltd.		<input type="checkbox"/>
30	DE	4,038,203		06-04-1992	Bonnacker et al.		<input type="checkbox"/>
31	JP	62-67017		03-26-1987	Sawai et al.		<input type="checkbox"/>
32	WO	98/36733		08-27-1998	Kamm, Michael Albert et al.		<input type="checkbox"/>

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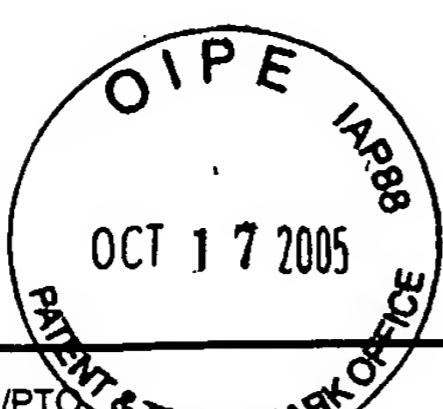
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
Sheet	2	of	7	Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1654
				Examiner Name	Tate, Christopher Robin
				Attorney Docket Number	010692-004532US

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33	WO	95/06466	A1	03-09-1995	Koren Laboratories Pty., Ltd.	
34	ZA	77/01135		02-25-1977	Prinsloo, J.	
35	JP	04-091036		03-24-1996	Hashioka Tatsuya	
36	WO	87/03490		06-18-1987	Key Pharmaceuticals, Inc.	
37	WO	98/37886		09-03-1998	Antropoli	

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Substitute for form 1449B/PTC

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Sheet	3	of	8	Attorney Docket Number

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	38	Ahlner et al., "Organic Nitrate Esters: Clinical Use and Mechanisms of Actions." <i>Pharmacol. Reviews</i> 43(3):351-353 (1991).	
	39	Budavari et al. (Eds.), "The Merck Index." pp. 198 and 821 (isopropyl nitrate); 11th Edition, Merck & Co., Rahway, N.J. (1989)	
	40	Bult et al., "Nitric oxide as an inhibitory non-adrenergic non-cholinergic neurotransmitter." <i>Nature</i> , 345:346-347, 1990.	
	41	Burleigh, D. and D'Mello, A., "Physiology and Pharmacology of the Internal Anal Sphincter." Chapter 2, pages 22-41, in <u>Coloproctology and The Pelvic Floor</u> , Henry and Swash (Eds.), Butterworth Publishers, Stoneham, Mass., USA and London, England, ISBN 0-407-00352-5 (1985)	
	42	Burleigh, D., "Ng-Nitro-L-Arginine Reduces Nonadrenergic Relaxations of Human Gut." <i>Gastroenterology</i> , 102: 679-683 (1992)	
	43	Chakder, et al. "Release of nitric oxide by activation of nonadrenergic noncholinergic neurons of internal anal sphincter." <u>NO Release By Nanc Naural Stimulation and VIP</u> , G7-12 (1992)	
	44	Enck et al., "Spontaneous variation of anal 'resting' pressure in healthy humans." <i>Am. J. Physiol.</i> , 261(5 Pt 1):G823-G826 (1991)	
	45	Farouk et al., "Sustained Internal Sphincter Hypertonia in Patients with Chronic Anal Fissure." <i>Dis. Col. Rect.</i> , 37:424-429 (1994)	
	46	Feeisch et al., "Correlation between nitric oxide formation during degradation of organic nitrates and activation of guanylate cyclase." <i>Eur. J. Pharmacol.</i> , 139:19-30 (1987)	
	47	Fung et al., "Biochemical mechanism of organic nitrate action." <i>Am. J. Cardiol.</i> , 70:4B-10B (1992)	
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	49	Gillespie et al., "Influence of hemoglobin and erythrocytes on the effects of EDRF, a smooth muscle inhibitory factor, and nitric oxide on vascular and non-vascular smooth muscle." <i>Br. J. Pharmacol.</i> , 95:1151-1156, 1988.	
	50	Gorfine, SR., 1995, "Treatment of benign anal disease with topical nitroglycerin." <i>Dis. Col. Rect.</i> , 38(5):453-456	
	51	Guillermot et al., "Nitroglycerin In Situ Reduces Upper Anal Canal Pressure." <i>Digest. Dis. Sci.</i> , 37(1):155 (1992)	
	52	Guillermot et al., "Action of <i>in situ</i> nitroglycerin on upper anal canal pressure of patients with terminal constipation. A pilot study." <i>Dis. Col. Rect.</i> , 36(4):372-376 (1993)	

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				<i>Art Unit</i>	1654
				<i>Examiner Name</i>	Tate, Christopher Robin
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	53	Huff et al., (Eds.), "Physicians' Desk Reference." 41st Edition, Medical Economics Company, Oradell, N.J., at pp. 780, 1176-1178, 1533 and 1984-85 (1987)		T ²
	54	Ignarro et al., "Nitric oxide and cyclic GMP formation upon electrical field stimulation cause relaxation of corpus cavernosum smooth muscle." <i>Biochem. Biophys. Res. Commun.</i> , 170:843-850, 1990.		
	55	Jalan, K. et al., "Perineal Wound Healing in Ulcerative Colitis." <i>British Journal of Surgery</i> (October 1969) 56(10):749-53		
	56	Jensen, S. "Treatment of first episodes of acute anal fissure: Prospective randomized study of lignocaine ointment versus hydrocortisone ointment or warm sitz bath plus bran." <i>Br. Med. J.</i> , 292(6529):1167-9 (1986)		
	57	Keighley, R. and Williams, N. "Anatomy and Physiology." Chapter One, in <u>Surgery of the Anus, Rectum and Colon</u> , London, W.B. Saunders (1993)		
	58	Kennedy, M. et al, "Chemical Sphincterotomy for Anal Fissure – A New Treatment." Abstract CR33, presentation at Royal Australasian College of Surgeons at Hobart, Tasmania meeting of May 1-6, 1994		
	59	Kennedy, M. et al., "Glyceryl Trinitrate Ointment for the Treatment of Chronic Anal Fissure." <i>Dis Colon Rectum</i> 42(8):1000-1006 (August 1999)		
	60	Loder, P. et al, "Reversible chemical sphincterotomy' by local application of glyceryl trinitrate." <i>Br. J. Surg.</i> , 81: 1386-1389 (1994),		
	61	Loder, P. et al, "Topical Application of a Nitric Oxide Donor Reduces Internal Anal Sphincter Tone: Therapeutic Implications." <i>Gut</i> 34:S25 (1993) Abstract also published in AGA Abstracts, <i>Gastroenterology</i> , 104: A544 (1993)		
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	63	Lord, P., "A Day-Case Procedure for the Cure of Third-Degree Haemorrhoids." <i>Br. J. Surg.</i> 56(10):47-9 (1969)		
	64	Lubowski, D. et al., "Neural control of internal anal sphincter function." <i>Br. J. Surg.</i> 74: 668-670 (August 1987)		
	65	Lund, J. and Scholefield, J., "A randomised, prospective, double-blind, placebo-controlled trial of glyceryl trinitrate ointment in treatment of anal fissure." <i>Lancet</i> , 349: 11-14 (January 4, 1997)		
	66	Lund, J. et al., "Use of glyceryl trinitrate ointment in the treatment of anal fissure." <i>British Journal of Surgery</i> 83: 776-777 (1996)		
	67	MacDonald, A. et al., "Manual dilation of the anus." <i>British Journal of Surgery</i> 79:1381-1382 (December 1992)		
	68	<i>Mims Annual Drug Reference</i> , Fifteenth Edition, 2-75, page 2042 (1991)		

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	69	O'Kelley, T. et al, "Nerve mediated relaxation of the human internal anal sphincter: the role of nitric oxide." <i>Gut</i> , 34: 689-693 (1993)			
	70	Rattan, S. and Chakder, S., "Role of nitric oxide as a mediator of internal anal sphincter relaxation." <i>Am. J. Physiol.</i> G107-G112 (1992)			
	71	Rattan, S. et al., "Nitric Oxide Pathway in Rectoanal Inhibitory Reflex of Opossum Internal Anal Sphincter." <i>Gastroenterology</i> , 103: 43-50 (1992)			
	72	Shafik, "Role of warm-water bath in anorectal conditions: the thermospheric reflex." <i>J. Clin. Gastroenterol.</i> , 16:304-8 (1993)			
	73	Schouten, W.R. et.al. "Pathophysiological aspects and clinical outcome of intra-anal application of isosorbide dinitrate in patients with chronic anal fissure." <i>Gut</i> 39:465-9 (1996); see also: <i>Dis. Col. Rect.</i> , Apr. 1986, p. 18			
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	78	Bacher, H. et.al. "Local nitroglycerin for treatment of anal fissures: an alternative to lateral sphincterotomy?" <i>Dis. Col. Rect.</i> , 40:840-5 (1997)			
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	80	Corby, "Anal canal pressures are low in women with postpartum anal fissure." <i>Br. J. Surg.</i> , 84:86-8 (1997)			
	81	<i>Dictionnaire Vidal</i> , Ed. 1996, entries concerning Lenitral Percutane and Lenitral Spray (1996)			
	82	Dodi, "Hot or cold in anal pain? A study of the changes in internal anal spinchter pressure profiles." <i>Dis. Col. Rect.</i> , 29(4):248-51 (1986)			
	83	Farid, M. "Internal anal sphincter relaxation with topical nitroglycerin in the treatment of some benign anal conditions." <i>Br. J. Surg.</i> , 84:1 (1997)			
	84	Farouk, R. et.al. "Changing patterns of treatment for chronic anal fissure." <i>Annual Review College Surgeons England</i> ; 80:194-6 (1998)			

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	85	"Glyceryl trinitrate for anal fissure?" <i>Drug and Therapeutics Bulletin</i> ; 36:55-6 (1998)			
	86	Gorfine, S.R. "Topical nitroglycerin ointment for anal fissures and ulcers." <i>New England Journal of Medicine</i> ; 333: 1156-7 (1995)			
	87	Hattori, K. et.al. "Fissure treatment in day surgery days." Presented at the 1998 General Assembly of The Japan Society of Coloproctology (1998)			
	88	Hyman, N.H. et.al. "Nitroglycerin ointment for anal fissures: Effective treatment or just a headache?" <i>Dis. Col. Rect.</i> , 42:383-5 (1999)			
	89	Keck, "Computer-generated profiles of the anal canal in patients with anal fissure." <i>Dis. Col. Rect.</i> , 38(1):72-9 (1995)			
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	91	Lowenstein, B. et.al. Treatment of proctalgia fugax with topical nitroglycerin: report of a case. <i>Dis. Col. Rect.</i> ; 41:667-8. (1998)			
	92	Lund JN et al. "Follow-up of patients with chronic anal fissure treated with topical glyceryl trinitrate." <i>Lancet</i> , 352:1681 (1998)			
	93	Lysy, J. et.al. "Treatment of chronic anal fissure with isosorbide dinitrate: long-term results and dose determination." <i>Dis. Col. Rect.</i> , 41:1406-10 (1998)			
	94	Manookian, C.M. et.al. Topical nitroglycerin in the management of anal fissure: an explosive outcome! <i>American Surgeon</i> 64:962-4 (1998)			
	95	Maria, "Identification of anti-endothelial cell antibodies in patients with chronic anal fissure." <i>Surgery</i> , 126:535-40 (1999)			
	96	Mazier, "Hemorrhoids, fissures, and pruritus ani." <i>Anorectal Surg.</i> , 74(6):1277-92 (1994)			
	97	Oettle, G.J. et.al. "Glyceryl trinitrate vs. sphincterotomy for treatment of chronic fissure-in-ano: a randomized, controlled trial." <i>Dis. Col. Rect.</i> , 40:1318-20 (1997)			
	98	Pitt, J. et.al. "Chemical sphincterotomy for anal fissure." <i>Colorectal disease</i> 1998; 2-8.			
	99	Pitt, "Double-blind, randomized, placebo-controlled trial of oral indoramin to treat chronic anal fissure." ASCRS Meeting, June 2000, Poster Presentation P2 (2000)			
	100	Romano, "A critical appraisal of pathogenesis and morbidity of surgical treatment of chronic anal fissure." <i>J. Am. Coll. Surg.</i> , 178:600-4 (1994)			

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	101	Schouten, "Relationship between anal pressure and anodermal blood flow: The vascular pathogenesis of anal fissures." <i>Dis. Col. Rect.</i> , 37(7):664-9 (1994)		T ²
	102	Schouten, "Ischaemic nature of anal fissure." <i>Br. J. Surg.</i> , 83:63-5 (1996)		
	103	Simons, A.J. et al. "Glyceryl trinitrate for anal fissure." <i>Lancet</i> , 348:491-2 (1996)		
	104	Suda, K. et.al. "Application of nitroglycerin ointment on post-hemorrhoidectomy pain." Presented at the 1998 General Assembly of The Japan Society of Coloproctology (1998)		

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.